REMARKS

Reconsideration of this application is respectfully requested.

Upon entry of the foregoing amendment, claims 1-6, 9, 10, 17, and 18 are pending in the application, with claim 1 being the independent claim. Claim 1 is sought to be amended. Claims 4-6, 9, 10, 17, and 18 are currently withdrawn from consideration. Claims 19-25 are sought to be cancelled by the present amendment without prejudice to or disclaimer of the subject matter therein.

Claim 1 has been amended to clarify Applicants' invention. Specifically, claim 1 has been amended to insert the phrase "physiologically active" immediately prior to recitation of the N-tetrahydrofuranylcarbonyl-substituted peptide, to delete "wherein" prior to recitation of the 2,000 to 50,000 molecular weight copolymer, and to reformat the claim to group recitation of the 2,000 to 50,000 molecular weight copolymer with recitation of the N-tetrahydrofuranylcarbonyl-substituted peptide, all to more clearly indicate that when the claimed sustained release composition of the claim alternatively comprises the N-tetrahydrofuranylcarbonyl-substituted peptide or its acetate salt, the copolymer has a weight average molecular weight of 2,000-50,000. Support for these changes can be found in the specification as filed, e.g., at page 13, line 27, to page 14, line 20, and in claims 7, 8, and 16 as originally filed.

The amendments to claim 1 have been made to put this claim into better form for consideration on appeal, as required under 37 C.F.R. § 1.116(b)(2). Amended claim 1 was not presented earlier because Applicants believed that claim 1 was allowable in its previous form.

These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the following remarks, Applicants respectfully request that the Examiner reconsider all rejections and objections and that they be withdrawn.

Double Patenting

The Examiner rejects claims 1-3 under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claim 1 of U.S. Patent. No. 5,480,868. (Office Action, at page 2, lines 6-8.)

Applicants continue to request that the obviousness-type double patenting rejection be held in abeyance until all remaining rejections and objections have been withdrawn and there is an indication of allowable subject matter.

Rejections Under 35 USC 112, First Paragraph

The Examiner rejects claims 1-3 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. (Office Action, at page 2, lines 15-18.) Applicants respectfully traverse this rejection.

Specifically, the Examiner alleges that undue experimentation would be required to use the composition of claim 1 to antagonize LH-RH. (Office Action, at page 3, lines 12-14.)

Applicants contend that there is no burden of undue experimentation to make and use the LH-RH antagonist of claim 1. As the examiner has acknowledged, LH-RH receptors are known. Therefore, the activity of the peptide or composition of claim 1 could be readily tested in an animal model for a human subject to determine whether it acts as an LH-RH antagonist. As *In re Wands* has made clear, the requirement for experimentation does not meet the threshold for lack of enablement and bar patentability; rather, a lack of enablement exists when the level of experimentation is undue. Applicants urge that testing the peptide or composition of claim 1 in an animal or human does not constitute undue experimentation.

Applicants believe that the rejection of claims 1-3 under 35 U.S.C. § 112, first paragraph, has been overcome and respectfully request that the Examiner withdraw this rejection.

Rejections Under 35 USC 112, Second Paragraph

The Examiner rejects claims 1-3 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. (Office Action, at page 4, lines 3-5.)

Specifically, the Examiner contends that claim 1 recites that the copolymer must have a molecular weight of 5-25 K, and also recites that the polymer has a weight of 2000-50000. (Office Action, at page 4, lines 6-11.) The Examiner also contends that claim 1 recites the phrase "or its acetate salt" and that this phrase is allegedly unclear. (Office Action, at page 4, lines 12-15.)

Applicants have amended claim 1 to more clearly convey that the 2-50K molecular weight range recited for the copolymer applies only to the copolymer when it is in combination with the N-tetrahydrofuranylcarbonyl-substituted peptide or the peptide's acetate salt. Applicants have done this by amending claim 1 to omit the term "wherein" prior to recitation of the 2,000 to 50,000 molecular weight copolymer, and to reformat claim 1 to group recitation of the 2,000 to 50,000 molecular weight copolymer with recitation of the N-tetrahydrofuranylcarbonyl-substituted peptide or its acetate salt.

Applicants believe that the rejection of claims 1-3 under 35 U.S.C. § 112, second paragraph, has been overcome. Accordingly, Applicants respectfully request that the Examiner withdraw this rejection.

Rejections Under 35 USC 103

The Examiner rejects claims 1-3 under 35 U.S.C. § 103 as allegedly being unpatentable over Haviv, U.S. Pat. No. 5,110,904 ("Haviv"), in view of Deasy, U.S. Pat. No. 4,874,612 ("Deasy"), or Hutchinson, U.S. Pat. No. 4,789,726 ("Hutchinson"). (Office Action, at page 5, lines 7-8.)

Applicants submit that neither Haviv, Deasy, nor Hutchinson teach the use of polylactic acid/polyglycolic acid ("PLA/PGA") copolymers having terminal carboxyl groups, as recited in Applicants' claims. Neither Haviv nor Deasy specifically discloses a non-catalytic dehydrative polycondensation process using α-hydroxy acids for making PLA/PLG copolymers, which Applicants identify in the current application as a method for synthesizing PLA/PLG polymers having a terminal carboxyl group (as opposed to a ring-opening polymerization process using catalysts and beginning with a cyclic dimer, which Applicants identify as a method that produces polymers substantially *not* containing free terminal carboxyl groups. See page 15, lines 15-25, and page 16, lines 24-32, of Applicants'

specification as filed.) In fact, Haviv cites U.S. Pat. No. 3,773,919 ("Boswell") as describing suitable PLA/PGA polymers (see column 27, lines 5-12). Boswell, however, appears to teach away from the use of PLA/PGA copolymers having terminal carboxyl groups (see following discussion of Boswell). Hutchinson appears to disclose both a ring-opening polymerization process and a polycondensation process for making PLA/PGA copolymers, but discloses disadvantages for both (see, e.g., column 1, lines 45-68, and column 2, lines 19-59), and thus appears to teach away from use of either process.

Thus, Applicants submit that in view of Haviv, Deasy, and Hutchinson, either alone or in combination with one another, there would have been no reason for one of skill in the art to combine PLA/PGA copolymers having terminal carboxyl groups with physiologically active peptides, such as LH-RH antagonists, to arrive at Applicants' claimed sustained release preparations. Thus, Applicants submit that the claimed sustained release preparations would not have been obvious in light of Haviv, Deasy, and Hutchinson.

The Examiner also rejects claims 1-3 under 35 U.S.C. § 103 as allegedly being unpatentable over Haviv in view of Boswell, U.S. Pat. No. 3,773,919 ("Boswell"), and further in view of Deasy or Hutchinson. (Office Action, at page 6, lines 10-12.)

As discussed above, neither Haviv, Deasy, nor Hutchinson teach the use of polylactic acid/polyglycolic acid ("PLA/PGA") copolymers having terminal carboxyl groups, as required by Applicants' claims. Moreover, Boswell appears to teach a ring-opening polymerization process using catalysts as a method of making PLA/PGA polymers, which Applicants have identified as a method that produces PLA/PGA polymers that substantially lack free terminal carboxyl groups. Boswell thus appears to teach away from the use of PLA/PGA polymers having free terminal carboxyl groups.

Applicants submit that Boswell fails to correct the deficiencies of Haviv, Deasy and Hutchinson, and that the claimed sustained release preparations would not have been obvious in light of these four references.

Applicants believe that the rejection of claims 1-3 under 35 U.S.C. § 103 has been overcome and respectfully request that the Examiner withdraw this rejection.

Objection to the Claims

The Examiner objects to claim 1 on the basis that the structural formula in the claim is allegedly not clearly legible. (Office Action, at page 3, line 16.)

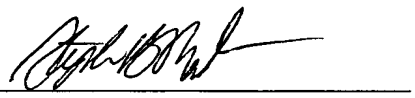
Applicants have amended the structural formulae in claim 1 to enhance their clarity. Accordingly, Applicants request that the Examiner withdraw the objection to claim 1.

CONCLUSION

For the foregoing reasons, Applicants respectfully request allowance of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

By 

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